

### **REMARKS**

Favorable reconsideration of the subject application is respectfully requested in view of the above amendment and the following remarks. Following the amendments, claims 2-17, 19-21 and 27-35 are under consideration, with claim 29 being in independent format.

Claims 1, 20 and 26 have been cancelled and claims 29-35 have been added. Newly added claim 29 recites an intracorporeal medical device and incorporates subject matter previously recited in claims 1, 20 (in part) and 26. Claims 2-5, 8, 11, 19, 27 and 28 have been amended to depend from claim 29, and claims 6, 7, 9, 10 and 12-17 have been amended to correspond to amended claims 5, 8, and 11. Claim 21 has been amended to recite the subject matter previously recited in claim 20, which is cancelled herein.

Dependent claims 30-35 are also new. Claim 30 recites a medical device of claim 29 wherein the support layer of the tubular structure is welded to the operating head; this feature is described in the subject application, as it was published, at paragraph 0042. Claim 31, also dependent on claim 29, recites that the support layer incorporates a less flexible support element at or near the bonding point; this feature is described in the subject application, as it was published, at paragraph 0043. Newly added claims 33-35 depend from claim 5 and recite various properties of the etches provided on a thermally shrinkable sheath; these features are described in the application, as it was published, at paragraph 0034. Claim 35, which is dependent on claim 28, has been added to specify that the mid section of the catheter includes a less flexible area that does not incorporate a support layer; this feature is described in the subject application, as it was published, at paragraph 0050.

It is urged that support for all the above amendments may be found throughout the specification as originally filed, and that none of the amendments constitute new matter or raise new issues for consideration. Applicant specifically reserves the right to pursue claims to any subject matter cancelled from the claims by the above amendments in one or more related applications.

Applicant wishes to thank the Examiner for the helpful telephone interview with his representative, Janet Sleath, on January 12, 2010.

**Claim rejections under 35 USC §102**

Claims 1-3, 19-21 and 26-28 stand finally rejected under 35 USC §102(b) as being anticipated by US Patent 5,501,694 to Ressemann et al. This rejection is respectfully traversed.

As noted above, claims 1 and 26 have been cancelled and the remaining claims, including the newly added claims, depend, either directly or indirectly, from newly added independent claim 29.

Independent claim 29 is drawn to an intracorporeal medical device comprising: (a) an operating head; (b) a catheter comprising a tubular structure, the tubular structure comprising: an overlying layer and a support layer defining an internal lumen, wherein the support layer comprises a contiguous coil element, a braid element or a weave element including a plurality of loops, and is attached to the overlying layer at a bonding point and not attached to the overlying layer along a free portion, whereby the support layer is slippable relative to the overlying layer along the free portion when the tubular structure is bent; and (c) a drive shaft that extends within the internal lumen of the catheter. The ability of the support layer to slip relative to the overlying layer when the tubular structure is bent, surprisingly provides a highly flexible structure with sufficient mechanical integrity and pushability to function as an interventional catheter. Tubular structures having this configuration also reduce the incidence of kinking, simply by virtue of the relative movement of the layers with respect to one another.

In the copy of Fig. 12 of Ressemann et al. provided on page 5 of the Office Action, the Examiner appears to indicate that element 182 or 178 of Ressemann et al. corresponds to the claimed overlying layer, and that element 94 corresponds to the claimed support layer. Applicant respectfully disagrees.

As stated in col. 11, lines 24-40, the device of Ressemann et al. includes a hollow drive shaft 92 which comprises “an inner coil 94, preferably formed from a plurality of intertwined strands of wire”. A wire braid 96 is applied over a portion of the outer diameter surface of coil 94 in order to limit radial and axial expansion of the inner coil 94. At col. 12, lines 45-49, Ressemann et al. state “the distal end 98 of the inner coil 94 is fixedly attached to the expandable material removal element 16 so that the drive shaft 92 and the material removal element 16 rotate conjointly”. Element 94 is thus clearly part of the drive shaft and cannot correspond to the presently claimed support layer.

With regards to element 182, applicant notes that this number is incorrectly used in Fig. 12 to represent two different elements and believes that this number should correctly be used to represent threads or grooves provided on a portion of the outer surface of the shoulder member 180 which extends from housing 36 (col. 19, line 66- col. 20, line 10). With regards to element 178, as stated, for example, at col. 9, lines 58-64, this represents a catheter assembly and thus cannot represent an overlying layer as currently claimed. Applicant notes that, at col. 12, lines 1-8, the reference teaches that a coating 100, such as sheath of a fluoropolymer, "is applied to the outer surface of the drive shaft 92". However, this also cannot correspond to either the outer layer or the support layer of the presently claimed device.

Applicant submits that the device of Ressemann et al. does not include all the elements of independent claim 29. Furthermore, it is urged that the teachings of Ressemann et al. would not have rendered the presently claimed intracorporeal medical device obvious to one of skill in the art at the time the presently claimed invention was made.

It is thus submitted that Ressemann et al. do not teach or suggest the subject matter recited in independent claim 29, and that the rejection of claims 1-3, 19-21 and 26-28 under 35 USC §102(b) can be properly withdrawn.

#### **Claim rejections under 35 USC §103**

Claim 4-17 stand finally rejected under 35 USC §103(a) as being unpatentable over US Patent 5,501,694 to Ressemann et al., either alone or in view of US Patent 6,143,013 to Samson et al. This rejection is respectfully traversed.

Following the above amendments, claims 4-17 all depend, either directly or indirectly from newly added independent claim 29. The disclosure of Ressemann et al., in particular as it relates to claim 29, is discussed above.

Samson et al. disclose a high performance braided catheter having a braided metallic reinforcing member positioned between a flexible outer tubing member and an inner tubing member to produce a catheter section that is flexible and kink resistant.

The Examiner asserts that Samson et al. teach a thermally shrinkable sheath having a plurality of etches for bonding to an adjacent layer, and further that Samson et al. teach a sheath comprising a polytetrafluoroethylene material and a support layer including a contiguous coil

element comprised of a wire and a plurality of gaps between each loop. The disclosure of Samson et al. does not overcome the deficiencies of Ressemann et al. discussed above.

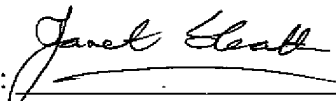
It is submitted that neither Ressemann et al. nor Samson et al., taken either singly or in combination, would have rendered the presently claimed invention obvious to one of skill in the art at the time the invention was made, and that the rejection of claims 4-17 under 35 USC §103(a) can therefore be properly withdrawn.

**Concluding Remarks**

A Request for Continued Examination, together with a request for a one month extension of time, extending the deadline for responding to the Office Action to February 9, 2010, are submitted herewith.

Every effort has been made to put the subject application in condition for allowance. Should the Examiner have any remaining concerns regarding this application, he is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

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